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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,767	CHIEN ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *40-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/05, 10/04, 9/04, 5/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I (claims 1-39) in the reply filed on August 7, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 40-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the inlet being connected via a collection duct, proximate to the collection needle (as recited in claim 4) is not disclosed in the detailed description in the specification. (The collection duct in the detailed description in the specification is disclosed as being between the screening capture device and the blood bag, rather than between a needle and the screening capture device—see for example page 17, paragraph [0071].)

Claim Objections

Claim 10 is objected to because of the following informalities: "or molecule" in line 3 should be deleted. Appropriate correction is required.

Claim 25 is objected to because of the following informalities: "process" in line 1 should be –processor--. Appropriate correction is required.

Claim 39 is objected to because of the following informalities: "is" in line 3 should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 17, 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 4 recite that the inlet is connected, via a collection duct, proximate to the collection needle. It is not clear whether or not the collection duct is part of the screening capture device. For purposes of examination, the claim will be interpreted to mean that the screening capture device is capable of being connected to a needle via a collection duct.

The term "low density" in claim 17 is a relative term which renders the claim indefinite. The term "low" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 19 recites that the first and second biochips comprise covalently attached analytes. It appears in claim 19 that the analyte is part of the biochip. However, it appears from Applicant's disclosure that the analyte is not part of the biochip but rather the biochip is intended for capturing an analyte. Thus it is not clear whether or not the analyte is part of the biochip. Clarification is requested.

Claim 36 recites the limitation "the attached analytes" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is also not clear as to what the analytes are attached. For examination purposes, the claim will be interpreted to mean that the analytes are attached to anything.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 10-17 and 22-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu, 6,924,107.

As to claim 1, Liu discloses a screening capture device for in-line screening of blood collected from a donor using a collection needle connected by a collection duct to a collection bag, comprising:

an inlet (52, see col. 7, line 44 and fig. 3), (or alternatively, the claimed inlet is the inlet connected to the top tubing of the 4D chip in fig. 12) for blood collected from the collection needle (it is noted the needle is not being claimed as part of the screening capture device, nor is it disclosed in the specification as being part of the screening capture device, and thus, the claim is interpreted to mean that the screening capture device has an inlet that is capable of collecting blood from a collection needle);

a biochip unit (i.e., biochip 20, see col. 6, line 45 and fig. 1; or alternatively, the 4D chip disclosed in figs. 4 and 9, comprising a plurality of biochips, see also col. 8, lines 25-29) that captures a target agent or molecule from the blood; and

an outlet (54, see col. 7, line 44, and fig. 3), (or alternatively, the claimed outlet is the outlet connected to the lower tubing of the 4D chip in fig. 12) that drains the blood from the screening capture device to the collection duct (it is noted that the collection duct is not being claimed as part of the screening capture device nor is it disclosed in the specification as being part of the screening capture device, and thus the claim is interpreted to mean that the outlet is capable of draining blood from the screening capture device to a collection duct).

As to claim 2, the inlet (52) of the screening capture device is capable of being directly connected to a rear end of the collection needle (it is noted that the needle is not claimed as part of the claimed invention, i.e., the screening capture device).

As to claim 3, the inlet of the screening capture device is capable of being connected, via a collection duct, proximate to the collection needle.

As to claim 4, the inlet is capable of being connected, via a collection duct, proximate to the collection needle so that the temperature of the blood in the screening capture device is approximately 37 degrees Celsius.

As to claim 5, the biochip unit that comprises a first biochip and a second biochip that are sequentially arranged between the inlet and the outlet (see fig. 4 and 9, disclosing multiple biochips forming a 4D chip; and fig. 11 and 12, showing that the 4D chip is connected to tubings at the top and bottom; and see col. 9, lines 13-21, disclosing an embodiment wherein the biochips are fluidly connected and sample flows in a single direction). (The claimed inlet is the inlet connected to the top tubing of the 4D chip in fig. 12 and the claimed outlet is the outlet connected to the lower tubing of the 4D chip in fig. 12).

As to claim 6, the first biochip and the second biochip are arranged in a parallel stacked fashion (see fig. 4 and 12).

As to claim 10, the screening capture device is capable of capturing a target agent or molecule that comprises at least one protein, nucleic acid molecule or fragment thereof indicative of or specific for a disease in a subject or an infectious agent. (The Office notes that Applicant has not recited any further structural limitations in claim 10,

nor how the target agent is captured or what structures allow for capturing the target agent.)

As to claim 11, the screening capture device is capable of capturing a target agent that is an antibody or antigen.

As to claim 12, the first biochip is capable of being a nucleic acid amplification technique (NAT) biochip designed to run multiple tests on the first chip. (The Office notes that Applicant has not recited any further structural limitations in claim 12, nor what structures allow for the nucleic acid amplification or multiple testing.)

As to claim 13, the first biochip is capable of capturing at least one infectious organism or cell containing a targeted nucleic acid molecule. (Applicant has not recited any structural limitations that allow for the capturing.)

As to claim 14, the infectious organism can be a virus or bacteria. (Applicant has not recited any structural limitations that allow for capturing of the virus or bacteria.)

As to claims 15 and 16, the second biochip is capable of performing multiple immunoassays and can capture targeted antigens and antibodies. (Applicant has not recited structural limitations that allow for the immunoassay intended use.)

As to claim 17, the first and second biochip are considered low density biochips (col. 6, line 61).

As to claim 22, the inlet and outlet are capable of being sealed when the screening capture device is removed from the collection needle and the collection duct. (Applicant has not claimed any structural limitations that seal the inlet or outlet).

As to claim 23, the top biochip (see fig. 11) is considered to be a lid and it is capable of being robotically removed. (Applicant has not claimed any structural element to the lid.)

As to claim 24, Liu discloses a screening system for in-line screening of blood collected from a donor using a collection needle connected by a collection duct to a collection bag, comprising:

a screening capture device for in-line attachment between the collection needle and the collection duct, the screening capture device comprising:

an inlet for blood collected from the collection needle (52, see col. 7, line 44 and fig. 3), (or alternatively, the claimed inlet is the inlet connected to the top tubing of the 4D chip in fig. 12) for blood collected from the collection needle (it is noted the needle is not being claimed as part of the screening capture device, nor is it disclosed in the specification as being part of the screening capture device, and thus, the claim is interpreted to mean that the screening capture device has an inlet that is capable of collecting blood from a collection needle);

a biochip unit (i.e., biochip 20, see col. 6, line 45 and fig. 1; or alternatively, the 4D chip disclosed in figs. 4 and 9, comprising a plurality of biochips, see also col. 8, lines 25-29) that captures a target agent or molecule from the blood; and

an outlet (54, see col. 7, line 44, and fig. 3), (or alternatively, the claimed outlet is the outlet connected to the lower tubing of the 4D chip in fig. 12) that drains the blood from the screening capture device to the collection duct (it is noted that the collection duct is not being claimed as part of the screening capture device nor is it disclosed in

the specification as being part of the screening capture device, and thus the claim is interpreted to mean that the outlet is capable of draining blood from the screening capture device to a collection duct);

and at least one biochip processor (i.e., one of the chambers, 60) for detecting at least one captured target agent or molecule.

As to claim 25, the biochip processor is capable of amplifying said target agent or molecule.

As to claim 26, the biochip processor is considered to be a sealed disposable unit (see fig. 3), (the processor is considered to be capable of being disposed) having a nucleic acid amplification technique (NAT) portion for processing a first biochip and an immunoassay portion for processing a second biochip.

As to claim 27, the system is capable of capturing a nucleic acid molecule (it is noted that Applicant has not recited how the nucleic acid molecule is captured), and the NAT portion comprises:

a biochip holder (any portion of "biochip holder" in fig. 12);

at least one reservoir (any of chambers 60) for holding a sample;

at least one amplification reaction chamber (any of the other chambers 60) connected to the reservoir (see fig. 3); and

at least one detection component (capillary 50) connected to the amplification reaction chamber. (It is noted that Applicant has not recited any structural limitations of the detection component.)

As to claim 28, the device further comprises:

at least one reagent container (any of the other chambers 60, see fig. 3) connected to the reservoir; and at least one reagent container (any of the other chambers 60, see fig. 3) connected to the reaction chamber.

As to claim 29, the NAT portion further comprises the first biochip (fig. 3) held in the biochip holder (any portion of "biochip holder" in fig. 11).

As to claim 30, the first biochip is held such that a surface is capable of containing analytes in contact with at least one elution and lysing buffer.

As to claim 31, the detection component is at least one microfluidity chamber (any of the chambers 60, see fig. 3).

As to claim 32, there are more than one biochip processors (see the plurality of chambers 60 in fig. 3).

As to claim 33, system is capable of capturing a target antibody or a target antigen, and the immunoassay portion comprises:

a biochip holder (any other portion of "biochip holder" in fig. 11);

at least one reservoir for holding a sample (one of the chambers 60 in fig. 3 in one of the biochips in fig. 11);

at least one reaction camber (one of the other chambers 60 in fig. 3 in one of the biochips in fig. 11) connected to the reservoir; and

at least one detection component (one of the other chambers 60 in fig. 3 in one of the biochips in fig. 11) connected to the reaction chamber.

As to claim 34, the immunoassay portion further comprises:

at least one reagent container (one of the chambers 60 in fig. 3 in one of the biochips in fig. 11) connected to the reservoir; and

at least one reagent container (one of the other chambers 60 in fig. 3 in one of the biochips in fig. 11) connected to the reaction chamber.

As to claim 35, the immunoassay portion further comprises: the second biochip held in the biochip holder (one of the biochips in the biochip holder in fig. 11).

As to claim 36, the second biochip is capable of being held such that analytes are in contact with at least one buffer.

As to claim 37, the detection component is at least one microfluidity chamber (one of the chambers 60 in fig. 3).

As to claim 38, there is at least two reaction chambers (60, fig. 3), one for the detection of a target antibody and one for the detection of a target antigen.

As to claim 39, each reaction chamber is connected to at least one detection component comprising at least one microfluidity chamber (one of the other chambers 60 in fig. 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liu, 6,924,107, in view of Chee et al., 5,861,242.

Liu discloses the invention substantially as claimed (see above regarding claims 1 and 5), except for the first and second biochips comprising microarrays in which the analytes that bind to the target agent or molecule, if present in the blood, are arranged along the length of the biochip in the direction of blood flow over the first and second biochips, respectively.

However Chee et al. teach that chips can include an array of probes which allow full-sequence determination of ribosomal RNA or DNA of pathogens (col. 12, lines 32-35). The full sequence of the ribosomal RNA or DNA is compared against a database of the sequence of thousands of known pathogens for detection of a disease (col. 12, lines 48-52). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an array of probes as taught by Chee et al. in the Liu biochips because Chee et al. teach that an array of probes provide the advantage of allowing for full-sequence determination of ribosomal RNA or DNA of pathogens, as would be desirable for the detection of a disease.

Claims 7-9, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu, 6,924,107, in view of Narang et al., 6,020,209.

Liu discloses the invention substantially as claimed (see above).

As to claim 19, Liu does not disclose that the first and second biochips comprise covalently attached analytes. However, Narang et al. teach a chip with immobilized antibody molecules for immunoassay purposes (col. 5, line 60 – col. 6, line 19; and col. 4, lines 62-67.) Narang et al. also teach that the antibodies are immobilized by covalent bonding (col. 5, lines 12-14). It would have been obvious to one of ordinary skill in the art at the time the invention was made to immobilize antibody molecules as taught by Narang et al. in the Liu biochip because Narang et al. teach that immobilized antibody molecules in a chip allow for performing immunoassays. The analyte (antigen) is at the least indirectly covalently bound to the biochip because the antibody is disclosed to be covalently bound to the chip (col. 5, line 12-14).

As to claim 21, Liu also does not disclose that the device further comprises an anti-backflow device that prevents the blood from flowing back towards the inlet. However Narang et al. teach a biochip with valves and pumps for fluid control and still produce a small, lightweight flow immunosensor (col. 5, lines 57-59). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a valve as taught by Narang et al. in the Liu biochip because Narang et al. teach that a valve, in addition to pumps, allow for fluid control, as would be desirable in performing immunoassays. The valve is considered to be an anti-backflow device. (Applicant has not recited any structural limitations relating to the anti-backflow device.)

As to claim 7, while Liu does not teach that the dimensions of the screening capture device are such that a flow rate of blood flowing through the screening capture device is equal to the flow rate of the collected blood in the absence of the screening

capture device, Narang et al. however teach use of pumps for fluid control and still produce a small, lightweight flow immunosensor (col. 5, lines 57-59). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a pump as taught by Narang et al. in the Liu biochip because Narang et al. teach that a pump allows for fluid control, as would be desirable for convenience and for performing immunoassays. With the Liu biochip modified by Narang et al. to provide for a pump, the dimensions of the capillaries (50) in the Liu biochip is capable of allowing a flow rate as recited by Applicant. (The Office notes that Applicant's claim do not exclude this embodiment.)

As to claim 8, Liu does not teach that the dimensions of the screening capture device are such that the flow rate of blood flowing through the screening capture device is about 450 ml per 10 minutes. However, with the Liu biochip modified by Narang et al. to provide for a pump, the dimensions of the capillaries (50) in the Liu biochip is capable of allowing a flow rate as recited by Applicant.

As to claim 9, Liu does not teach that the dimensions of the inlet, the outlet, a surface area of biochips in the biochip unit, and the screening capture device case are such that the collected blood maintains a constant flow rate through the screening capture device. However, with the Liu biochip modified by Narang et al. to provide for a pump, the dimensions of the capillaries (50) in the Liu biochip is capable of allowing a flow rate as recited by Applicant.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liu, 6,924,107, in view of Bashir et al., US 2001/0053535, and further in view of Yamanishi et al., US 2003/0134416.

Liu discloses the invention substantially as claimed (see above), except for the outlet including a funnel and a filter.

However, Bashir et al. teach separating of contaminants from a fluid sample on the biosensor chip by trapping the material of interest, that may be immobilized on carrier elements, in a detection chamber on a biosensor chip while flushing remaining portions of the fluid sample from the chamber. Bashir et al. teach that this trapping of the material of interest in a detection chamber serves in part to concentrate the material of interest and thus enhance the sensitivity of the detection technique. Bashir et al. teach that the trapping may be implemented in part by providing a filter barrier or retention structure at an outlet of the detection chamber (paragraph [0025]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a filter barrier as taught by Bashir et al. in the Liu biochip for use as a detection chamber as taught by Bashir et al. because Bashir et al. teach that the filter provides the advantage of concentrating the material of interest and allowing for detection and also enhancing the sensitivity of the detection technique.

Moreover, Yamanishi et al. teach that in fabricating filter slots, the slot can be tapered so that the sample goes through the narrow-width side first and then filtered cells exit at the wide-width side of the slot so that trapping of cells are avoided as they are being filtered. Yamanishi et al. also teach that the orientation of the filter can be

such that the wide-width side of the filter slots faces the sample (paragraph [0199]). (The tapered slot is considered by the Office to be a funnel because it has the shape of a funnel.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a tapered slot as taught by Yamanishi et al. in the Liu invention as modified by Bashir et al. providing a filter because Yamanishi et al. teach that the tapered slot provides the benefit of preventing trapping of materials such as cells as they are being filtered, as would be desirable for preventing a clog in the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9/16/06
Ann Lam